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REMARKS

In the Office Action Office Action dated July 20, 2006 claims 1, 3, 4, 7 – 9, 11, 12, 14, 28, and 35 are pending of which claims 1, 3, 4, 7 – 9, 11, 12, 14, 28, and 35 were rejected.

In particular, claims 1, 4, 8, 9, 12, and 14 were rejected under 35 USC 103(a) as being unpatentable over Rodriguez (US Patent 5421349) in view of Lafontaine (US Patent 5662621) and further in view of Worley (US Pub 20030208141). Claims 3, 28 and 35 were rejected under 35 USC 103(a) as being unpatentable over Rodriguez (US Patent 5421349) in view of Lafontaine (US Patent 5662621) and further in view of Worley (US Pub 20030208141) as applied to claim 1 and further in view of Cornelius (US Pat 5924998). Claims 7 and 11 were rejected under 35 USC 103(a) as being unpatentable over Rodriguez (US Patent 5421349) in view of Lafontaine (US Patent 5662621) and further in view of Worley (US Pub 20030208141) as applied to claim 1 and further in view of Erickson et al (US 566458).

The examiner has also raised an issue in relation to the claimed priority date. We submit that this is not an issue with respect to the prior art items Rodriguez (US Patent 5421349), Lafontaine (US Patent 5662621), Erickson et al (US 566458), Worley (US Pub 20030208141) and Cornelius (US Pat 5924998) as their claimed priority dates are all before that of the present application. As we have discussed below these references are not in fact relevant to the present application. In relation to the previously raised Connors et al (US Patent 20040039304) which has a claimed priority date between the date of filing the present provisional and the non-provisional applications we submit that this reference is currently not raised against any of the claims and therefore can be disregarded. We submit therefore that the priority date is an issue that can be decided by a court if and when it needs

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to be confirmed but that for the determination of the anticipation and patentability of the present claims the matter does not need to be addressed further.

No amendments are made with this response.

Claim 1 was rejected under 35 USC 103(a) as being unpatentable over Rodriguez in view of Lafontaine (US Patent 5662621) and further in view of Worley (US Pub 20030208141).

Claim 1 as previously amended defines a guide wire which has three distinct zones each of which has a specific characteristic and in particular the proximal and distal zones are more clearly defined. The proximal zone is specifically formed as described in claim 1 as having a transition from high stiffness to semi stiffness so as to be able to be deployed into the nose cone of an endovascular deployment device without spearing into the sides of a lumen of a guide wire catheter (see page 10 line 29 to page 11 line 9) and particularly into the nose cone dilator region of an endovascular deployment device which is formed from relatively soft elastomeric materials. The central zone is of high stiffness and constant diameter to assist with deployment of the endovascular deployment device over it by being stiff enough to straighten the vasculature (page 10 lines 3 to 6). The distal zone has a pre-formed curve to enable it to take up the shape of the thoracic arch of a patient (page 10 lines 10 to 13) and to anchor the guide wire into the aorta during advancement of the endovascular deployment device (page 9 lines 18 to 22). The distal zone is also formed into three zones of reducing stiffness from the central zone. A semi-stiff zone, a transition zone and a tip zone of high flexibility zone. The tip zone has a tip curve and is highly flexible to avoid damage to the vasculature and particularly the aortic valve of the heart (page 9 lines 22 to 27). We submit that the combination of all of these features is not present in any one of Rodriguez, Lafontaine or Worley or a combination of them.

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Rodriguez (US Pat 5421349) discloses a guide wire which has a central portion which while being described as being stiffer than the distal tip is clearly illustrated as being relatively flexible, there is certainly no teaching or suggestion of high stiffness as is suggested by the examiner. The proximal tip of the Rodriguez device is very short, "three quarters to one and a half inches" (column 2 lines 43 to 44) and preferably has a blunt tip of greater diameter than the wire diameter so that it can be pushed by a gloved hand. See column 2 lines 36 to 44. This size and shape of proximal tip is clearly not intended to be for use on a guide wire over which a deployment device can be advanced in the vasculature of a patient. This can be understood further because the central portion appears to have a region of protrusion (item 19 in Figure 1) and the description at column 3 line 67 to column 4 line 1 describes the use of the device to push a coil through the vasculature of a patient. Further, Rodriguez does not disclose or teach a guide wire which has an elongate central zone of high stiffness and substantially constant diameter along its length to straighten out the vasculature, a proximal zone of transition from high stiffness to semi-stiffness and having a length of from 3 cm to 20 cm to be able to be fed back through the guide wire catheter of an endovascular delivery device and a distal zone having three zones of transition from high stiffness to being relatively flexible and in which the distal zone has a pre-formed curve with a radius of curvature of from 5 cm to 15 cm to hook into the thoracic arch and also a tip curve with a radius of curvature of from 5 to 20 mm to prevent damage to the vasculature and heart valves.

Lafontaine discloses a guide catheter and not a guide wire. The guide catheter has a lumen therethrough through which can be deployed a guide wire or other therapeutic device. The guide catheter is formed from a shape memory material and has three heating zones. It is preformed into a selected shape and then straightened for use by heating. When cooled within the body of a patient it

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takes up its preformed shape so that a device can be extended through the catheter and can be directed as desired. There is no teaching or suggestion of the use a preformed curve at the distal end of a guide wire. The examiner states that Lafontaine includes heating coils for heating the zones thus varying their stiffness. There is not teaching in this disclosure and there is no reason to infer, as the examiner has, that any one of these zone has a stiffness when heated which is different from any other of the zones. Claim 1 particularly calls for the distal zone to have a semi-stiff zone, a transition zone and a tip zone of high flexibility zone consecutively. There is also no teaching or suggestion in Lafontaine that each of the heating zones has a different flexibility than other of the zones and certainly no teaching or suggestion that they have the varying stiffnesses claimed in claim 1.

Worley does not disclose a guide wire but a guide catheter or guiding introducer for introducing specialized medical devices into the coronary sinus (paragraph [0002]). The device of Worley is not a guide wire but in fact has lumen (para [0056]) for introducing devices such as a pacemaker lead (para [0056]) or a guide wire (para [0057]). A physician wishing to learn about guide wires would not learn anything of relevance to the present invention from a device for introducing guide wires. Nevertheless, the device of Worley does have a distal curve. But the distal curve of Worley does not have varying flexibilities along its length as is claimed in the present application. The main length of the catheter is formed from polyethylene or polyurethane and the distal tip can be more pliable (para [004]) but there is no teaching or suggestion of the varying stiffness at the distal zone as is claimed in the present invention.

Overall none of the three references cited by the examiner either in themselves or in combination teach or suggest the set of features of claim 1. In particular none of the references teach or suggest a proximal end over which can be introduced an endovascular introducer. Rodriguez has a proximal end adapted

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for striking with the gloved hand, Lafontaine has all its electrical controls at its distal end and Worley has a socket for introduction of a guide wire or other device into it. At the distal zone none of the three cited references teach or suggest a range of varying stiffnesses. Rodriguez merely has a tip of greater flexibility, Lafontaine has zones of varying stiffness modified electrically but not in the graded manner of the present invention. And Worley has only one stiffness except at the distal tip.

We submit that claim 1 is patentable over Rodriguez in view of Lafontaine (US Patent 5662621) and further in view of Worley (US Pub 20030208141).

Claims 4, 8, 9, 12, and 14 depend from patentable claim 1 and are, we submit themselves patentable over Rodriguez in view of Lafontaine (US Patent 5662621) and further in view of Worley (US Pub 20030208141).

Claims 3, 28 and 35 were rejected under 35 USC 103(a) as being unpatentable over Rodriguez in view of Lafontaine (US Patent 5662621) and further in view of Worley (US Pub 20030208141) as applied to claim 1 and further in view of Cornelius (US Pat 5924998). These claims, however, depend from patentable claim 1, and are, we submit themselves patentable.

Claims 7 and 11 were rejected under 35 USC 103(a) as being unpatentable over Rodriguez in view of Lafontaine (US Patent 5662621) and further in view of Worley (US Pub 20030208141) as applied to claim 1 and further in view of Erickson et al (US 566458). These claims, however, depend from patentable claim 1, and are, we submit themselves patentable.

The reexamination and reconsideration of this application is respectfully requested and it is further requested that this application be passed to issue.

Although the foregoing discussion is believed to be dispositive of the issues in this case, applicants' attorney requests a telephone interview with the Examiner

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to further discuss any unresolved issues remaining after the Examiner's consideration of this amendment.

Respectfully submitted,

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